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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,694	06/15/2001	Jon Duvick	35718/208255 (5718-111C)	1574

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,694	Applicant(s) DUVICK ET AL.	
	Examiner Medina Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 0615* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-20, pending in this application, are under examination.

Sequence Listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

No IDS is filed with this application.

Drawings

1. The drawings filed with this application have been approved.

Claim Rejections - 35 USC § 112

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 19, "fungus producing fumonisin" should be changed to ---fumonisin producing fungus--- or ---fungus that produce fumonisin--, for clarification.

In claim 1, line 6, ---a sequence encoding a polypeptide having --- should be inserted before "amine", for clarification.

In claims 1, part(c), and part (iii) of claims 10 and 18, the recitation of "stringent conditions" without specifying the specific hybridization and wash conditions required for "stringent" renders the claims indefinite. Dependent claims 2-9, 11-17, and 19-20 are included in the rejection.

In claims 1, part(d), and part (iv) of claims 10 and 18, "encoded by" should be replaced with ---encoding---, for clarification.

In claim 8, " promoters" lack antecedent basis in claim 1.

In claim 9, "sequence" should be changed to ---sequences---.

In claims 10, 18, 19, and 20, part (a),"or" before "amine"should be replaced with ---and--- ; and ---a sequence encoding a polypeptide having---, should be inserted.

In claims 2-3 and 11-12, "ESP1" or " BEST1" or "APAO" are not defined in the specification. It is unclear what each abbreviation stands for. Each should be spelled out in claims 2 and 3.

In claim 9, "sequence" should be changed to ---sequences---, for clarification.

Claim 13 is indefinite in the recitation of "the method of claim 10" because claim 10 is not drawn to a method.

In claim 17, The transformed seed" lacks antecedence.

Claim Rejections - 35 USC § 112

3. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing pathogenicity of a fungus producing fumonisin in a plant/plant cell by stably incorporating into the genome of a plant/cell specific fumonisin esterase or amine oxidase encoding sequences from *Exophiala spinifera* and *Rhinocladiella atrovirens* or the bacteria of ATCC 55552 isolates from maize seed, and the nucleotide sequence of SEQ ID NO:2, 4, 7, or 10 encoding the polypeptide set forth in SEQ ID NO:3, 5, 8, or 11, does not

reasonably provide enablement for a method that employs all fumonisin esterase or all amine oxidase encoding sequences and nucleotide sequences having at least 70% or 80% sequence identity to SEQ ID NO:2, 4, 7 or 10 or hybridizing sequences thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims a method of reducing pathogenicity of a fungus producing fumonisin comprising stably incorporating into the genome of a plant cell a primary nucleotide sequence comprising a sequence from any source encoding a polypeptide having esterase or amine oxidase activity and a secondary nucleotide sequence comprising the sequence of SEQ ID NO:2, 4, 7 or 10 or sequences having 70% or 80% sequence identity thereof or a sequence that hybridizes under undefined stringent conditions to the complement of SEQ ID NO:2, 4, 7 or 10 and still encoding a polypeptide having fumonisin detoxification activity. The claims also encompass a plant and a plant cell having stably incorporated into their genome said primary and secondary sequences. In contrast, the specification disclosed a method that employed nucleotide sequences from *Exophiala spinifera* (ATCC Accession No. 74269) and *Rhinocladiella atrovirens* (ATCC Accession No. 74270) or the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding fumonisin esterases of ESP1 or BEST1 and fumonisin APAO (US Patent 6, 229, 071 incorporated by reference) to reduce pathogenicity of a fungus producing fumonisin in fusarium sensitive crop plant/plant cells. Applicant has not provided guidance for the obtention of other fumonisin esterase or amine oxidase encoding sequences or a method for their use to reduce

fungal pathogenicity in exemplified or non-exemplified plant cells. While fumonisin degrading enzymes can be obtained from a variety of sources, not all isolates are able to degrade fumonisin. For example, US PAT. 6, 025, 188, teaches that several other Exophiala species (other than E. Exophiala) and non-maize Rhinocladiella isolates didn't degrade fumonisin or fumonisin related compounds (column 7, lines 4-9). Applicant has provided guidance for the isolated sequences of SEQ ID NO:2, 4, 7 or 10 encoding fumonisin-induced metabolic transporters, which may be used in combination with ESP1 (or BEST1) and APAO encoding sequences to affect detoxification/degradation of fumonisin. However, Applicant has not provided guidance for any modifications to SEQ ID NO:2, 4, 7 or 10 which resulted sequences having at least 70% or 80% sequence identity thereto and still encoding a polypeptide having fumonisin detoxification or degrading activity. It is unclear if any nucleotide sequence that hybridizes to the complement (fully or partially) of SEQ ID NO:2, 4, 7, or 10 or any sequence having at least 70% or 80% sequence identity thereto would encode a polypeptide having fumonisin /detoxification degrading activity. The state of the prior art teaches that sequence identity does not necessarily mean similar function. For example, Lazar et al. (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U))), teach a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al (Science, 13 November 1998, Vol. 282, pp. 131-133 (V) teaches as few as four amino acid substitutions can change an oleate 12-desaturase activity to a hydroxylase (Abstract). Applicants should note that the nucleic acids encoding Lazar's and Broun's proteins (mutated and original) would have more

than 70% and 80% sequence identity and would hybridize to each other under any stringent conditions. Therefore, it is unpredictable whether any nucleotide sequence that shares 70% or 80% sequence identity to the disclosed sequence or that hybridizes thereto under stringent conditions would encode a protein having detoxification/degrading fumonisin activity in transgenic plants, especially when coexpressed with other enzymes.

Therefore, given the breath of the claims; lack of guidance; unpredictability; the state of the art as discussed above; and lack of working examples, undue trial and error experimentations would have been required by one skilled in the art to practice the invention as broadly claimed.

Written Description

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a method of reducing pathogenicity of a fungus producing fumonisin comprising stably incorporating into the genome of a plant cell a primary nucleotide sequence comprising a sequence from any source encoding a polypeptide having esterase or amine oxidase activity and a secondary nucleotide sequence comprising the sequence of SEQ ID NO:2, 4, 7 or 10 or sequences having 70% or 80% sequence identity thereof or a sequence that hybridizes under stringent conditions to the complement of SEQ ID NO:2, 4, 7 or 10 and encoding a polypeptide having fumonisin detoxification activity. The claims also encompass a plant and a

plant cell having stably incorporated into their genome said primary and secondary sequences. These are genus claims. The specification described nucleotide sequences from *Exophiala spinifera* (ATCC Accession No. 74269) and *Rhinocladiella atrovirens* (ATCC Accession No. 74270) or the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding a polypeptide having fumonisin esterase or APAO activity and sequences of SEQ ID NO:2, 4, 7 or 10 encoding 3, 5, 8 or 11. The specification does not disclose any specific structural, physical and/or chemical properties common for all fumonisin esterase or amine oxidase encoding sequences. Neither the instant specification nor the prior art disclosed a consensus sequence common to all fumonisin esterase or amine oxidase which is a substantial portion of the sequence and which would allow one skilled in the art to predictably determine what will be the structure of the non-disclosed sequences. Therefore, the disclosure of nucleotide sequences from *Exophiala spinifera* (ATCC Accession No. 74269) and *Rhinocladiella atrovirens* (ATCC Accession No. 74270) or the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding a polypeptide having fumonisin esterase or APAO activity and sequences of SEQ ID NO:2, 4, 7 or 10 encoding 3, 5, 8 or 11 would not provide adequate written description for the claimed genus, a nucleotide sequence comprising a sequence encoding a polypeptide having fumonisin esterase or amine oxidase activity and sequences having 70% or 80% sequence identity SEQ ID NO:2, 4, 7 or 10 or a sequence that hybridizes thereof stringent conditions to the complement of and encoding a polypeptide having fumonisin detoxification activity. Because Applicant has not described the nucleotide sequences, a method that employs said sequences and plant or plant cells

comprising them are not similarly described. Therefore, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the invention as broadly claimed.

Weighing all above factors, the written description requirement is not satisfied. See Written Description Requirement published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

Remarks

Claims 1-20 are free of the prior art of record.

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00AM to 4:00PM and Wednesday-Thursday from 9:00AM to 3:00 PM .

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

August 20, 2002
mai

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600